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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,687	09/28/2000	David Wallach	WALLACH=25	7238

1444 7590 10/01/2004

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 09/671,687	<b>Applicant(s)</b> WALLACH ET AL.	
	<b>Examiner</b> David A. Lambertson	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-4, 20-24, 38-40 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 4, 20-24, 38-40 and 42-47 is/are rejected.
- 7) ☒ Claim(s) 3 and 48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed September 9, 2004. Amendments were made to the claims.

Claims 2-4, 20-24, 38-40 and 42-48 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed May 5, 2004, that is not addressed in this action has been withdrawn.

Because the prior Office Action was FINAL, and because the instant Office Action raises new rejections that are not necessitated by amendment, the finality of the previous Office Action has been withdrawn in favor of the instant Non-final Office Action.

The Office regrets the delay in instituting the following rejections. The previous prior art searches should have produced the following pieces of prior art; unfortunately, the references were not found upon the initial search of SEQ ID NO: 3.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following rejections are predicated on the determination that SEQ ID NO: 3, as recited in the claims, has an effective filing date of September 28, 2000. This is because the application to which it claims priority (09/646,403) does not disclose SEQ ID NO: 3.

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 2, 4, 20 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagase *et al.* (*DNA Res.* 5: 355-364, December 1998; see entire document; henceforth Nagase).

**This is a new rejection that is not necessitated by amendment.**

Nagase teaches the identification of KIAA0849 (see for example Table 2 on page 358); the sequence of KIAA0849 was submitted to EMBL on February 9, 1999 as Accession No. AB020656. The sequence of KIAA0849, at the time it was originally submitted, was 100% identical to amino acids 446 through 949 of SEQ ID NO: 3 of the instant specification. As such, KIAA0849 as disclosed in Nagase represents a fragment of SEQ ID NO: 3. Absent evidence to the contrary, and given no teaching in the instant specification as to where the TRAF2 or NF- $\kappa$ B complex subunit binding domains of SEQ ID NO: 3 are located, it is believed that KIAA0849 binds to TRAF2 and NF- $\kappa$ B complex subunits, thereby satisfying the functional requirement of the claim.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2, 4, 20, 38-40, 42, 43 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Bignell *et al.* (*Nature Genetics* 25: 160-165, June 2000; see entire document; henceforth Bignell). **This is a new rejection that is not necessitated by amendment.**

Bignell teaches the identification of the human *CYLD* gene (see for example Table 4, page 164), which has 98.8% homology with SEQ ID NO: 3 of the instant specification. Indeed, *CYLD* has only 7 amino acids that are different from SEQ ID NO: 3. Therefore, the *CYLD* gene described by Bignell anticipates a variant of SEQ ID NO: 3 having as much as 95% homology to SEQ ID NO: 3. Furthermore, due to the high degree of similarity between SEQ ID NO: 3 and

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*CYLD*, it is believed that *CYLD* binds to TRAF2 and the subunits of the NF- $\kappa$ B complex in the same manner as SEQ ID NO: 3, absent clear evidence to the contrary.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagase in view of Applicant's admission in the paper filed September 23, 2002 (see for example pages 2-6) that it would be obvious for one of skill in the art to make antibodies to a protein that is known in the prior art. **This is a new rejection that is not necessitated by amendment.**

Specifically, Nagase teaches a polypeptide sequence that has 100% identity to a fragment of SEQ ID NO: 3. However, Nagase does not teach making antibodies to this polypeptide.

It would have been obvious to make antibodies to the polypeptide taught by Nagase because Applicant concedes that such an endeavor is obvious (see for example page 3, first full paragraph of Applicant's response filed September 23, 2002). Motivation to make the antibodies would be to immunopurify the protein or to block its activity, again as per Applicant's admission (see for example page 4, the bottom of the paragraph bridging pages 3-4 of Applicant's response filed September 23, 2004). Although claims 44-46 are directed to antibodies that specifically bind to SEQ ID NO: 3 (a protein that is not anticipated by Nagase), it should be noted that antibodies to the portion of SEQ ID NO: 3 taught by Nagase (i.e., amino acids 446-949) will also

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bind to SEQ ID NO: 3. In other words, antibodies directed to amino acids 1-10 as disclosed by Nagase will necessarily bind to the portion of SEQ ID NO: 3 represented by amino acids 446-455 because of the 100% identity between the amino acid sequences. Furthermore, it is noted that since the polypeptide was known in the art, it would be obvious to make antibodies to this sequence (as per Applicant's admission) regardless of the functional limitation on the claimed protein, and these antibodies would necessarily bind to full length SEQ ID NO: 3 and specific fragments thereof.

Thus, absent evidence to the contrary, the ordinary skilled artisan would have been *expected* to make antibodies that bound to SEQ ID NO: 3 (or portions and variants thereof), as set forth by Applicant's admission concerning the production of antibodies.

Claims 21-24 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bignell in view of Applicant's admission in the paper filed September 23, 2002 (see for example pages 2-6) that it would be obvious for one of skill in the art to make antibodies to a protein that is known in the prior art. **This is a new rejection that is not necessitated by amendment.**

Specifically, Bignell teaches a polypeptide sequence that has 98.8% identity to SEQ ID NO: 3. However, Bignell does not teach making antibodies to this polypeptide.

It would have been obvious to make antibodies to the polypeptide taught by Bignell because Applicant concedes that such an endeavor is obvious (see for example page 3, first full paragraph of Applicant's response filed September 23, 2002). Motivation to make the antibodies would be to immunopurify the protein or to block its activity, again as per Applicant's admission (see for example page 4, the bottom of the paragraph bridging pages 3-4 of Applicant's response

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filed September 23, 2004). Although claims 44-46 are directed to antibodies that specifically bind to SEQ ID NO: 3 (a protein that is not anticipated by Bignell), it should be noted that antibodies to protein taught by Bignell (i.e., having 98.8% identity) will also bind to SEQ ID NO: 3. In other words, antibodies directed to amino acids 1-10 as disclosed by Bignell will necessarily bind to the portion of SEQ ID NO: 3 represented by amino acids 1-10 because of the 100% identity between the amino acid sequences. Furthermore, it is noted that since the polypeptide was known in the art, it would be obvious to make antibodies to this sequence (as per Applicant's admission) regardless of the functional limitation on the claimed protein, and these antibodies would necessarily bind to full length SEQ ID NO: 3 and fragments thereof.

Thus, absent evidence to the contrary, the ordinary skilled artisan would have been *expected* to make antibodies that bound to SEQ ID NO: 3 (or portions and variants thereof), as set forth by Applicant's admission concerning the production of antibodies.

#### ***Allowable Subject Matter***

Claims 3 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

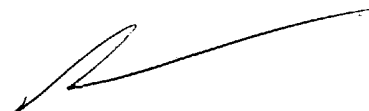
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.  
AU 1636



JAMES KETTER  
PRIMARY EXAMINER